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BARD

September 14, 1999

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, rm. 1-23
Parklawn Drive
Rockville, MD 20857

RE: Citizen Petition
Electrode Lead Wires and Patient Cables

Dear Sir or Madam,

Pursuant to 21 CFR 898.14, C.R. Bard, Inc. is submitting four copies of this citizens petition to request the Commissioner of Food and Drugs to issue an exemption to Bard, for certain devices, with respect to the *Performance Standard for Electrode Lead Wires and Patient Cables*.

C.R. Bard, Inc. is requesting an exemption from the mandatory *Performance Standard for Electrode Lead Wires and Patient Cables* for their Temporary Pacing Electrode Catheters.

It is the understanding of C.R. Bard, Inc. that an exemption is not effective until the agency approves the request under 21 CFR Section 10.30(e)(2)(i).

If you have any questions about this petition, please contact me at:

Bard Electrophysiology Division of C.R. Bard, Inc.
55 Technology Drive
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Telephone No.: 978-323-2216 (Direct Line)
Fax No.: 978-323-2222
e-mail: deborahherrington@crbard.com

Sincerely,

Deborah L. Herrington
Regulatory Affairs Manager

Bard *electrophysiology*

99P-4108

CP1

CITIZEN PETITION

A. Device Name and Indication(s) for Use

Classification Panel:	Part 870 - Cardiovascular Devices Subpart D - Cardiovascular Prosthetic Devices 870.3680 Cardiovascular permanent or temporary pacemaker electrode
Trade Name:	Temporary Pacing Electrode Catheter
Common/Usual Name:	Electrode, Pacemaker, Temporary
Classification Name:	Electrode, Pacemaker, Temporary
Product Code(s);	74 LDF
Indication(s) for Use:	Refer to Attachment 1 which provides a current instruction sheet which includes the Indication(s) for Use for the Bard Temporary pacing Electrodes included in this petition.

B. Action Requested

C.R. Bard, Inc. is requesting an exemption from the mandatory *Performance Standard for Electrode Lead Wires and Patient Cables* for their Temporary Pacing Electrode Catheters.

As indicated in 21 CFR, Part 898, ***electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in [Section] 898.12.***

Section 898.12 Performance Standard reads as follows: ***(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:***

International Electrotechnical Commission (IEC)
601-1: Medical Electrical Equipment
601-1 (1988) Part 1: General requirements for safety
Amendment No. 1 (1991)
Amendment No. 2 (1995)

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3 (c) of the standard set forth in paragraph (a) of this section.

C. Statement of Grounds

C.R. Bard, Inc. has been working towards compliance to the *Performance Standard for Electrode Lead Wires and Patient Cables* for all of the Bard devices impacted by this standard. C.R. Bard, Inc. is requesting an exemption from the mandatory *Performance Standard for Electrode Lead Wires and Patient Cables* for their Temporary Pacing Electrode Catheters (hereinafter referred to as TPE's) based on the following reasons.

1) ***Not all device interfaces are changing to comply with the standard.*** The Bard TPE's connect to external pulse generators. The manufacturers of external pulse generators are not bound to comply with the standard. The standard, as written, appears to apply only to the manufacturers of the electrode lead wires and patient cables and not to the manufacturers of the devices to which the lead wires and patient cables connect.

   Bard has had several discussions regarding this issue, with manufacturers of various pulse generators with which the Bard TPE's interface. Their position is that the standard does not apply to them. Their pulse generator devices are required to connect to and accept various connector designs varying from .020" - .090". As a result they have not and do not intend to modify the connection terminals on their devices to accept a protected lead wire or patient cable.

   One such manufacturer, Medtronic, which manufacturers both pulse generators and temporary pacing leads, filed and was granted an exemption for their Temporary Pacing Leads. Granting this exemption locks their current design of the interface (exposed .080" design) to their external pulse generator.

   In addition, there is no support to change some generator connections. There are a number of generators that remain in use in the field although the manufacturer is no longer in business. Therefore, there is no support to make the appropriate modifications to these devices that would allow compliance to the standard.

2) ***The development of a single universal adapter that complies with the IEC standard is virtually impossible due to the variety of device interfaces that are available.*** There is no standardization that applies to the manufacturers of external pulse generator connectors. This makes it impossible to develop a single protected adapter which would connect to our protected catheter lead wire; a variety of adapters would be required. Lead wires from many different manufacturers are used in a clinical setting. This would result in the need for multiple adapters for use with the various lead wires. Also, Bard's solution to a universal adapter may not agree with that of another manufacturer.

Bard believes that the necessity of using various adapters poses an unnecessary risk to the patient in an emergency room setting. In the critical environment in which these devices are used time is of the essence. Any number of lead wires from various manufacturers could be available for use, thus the need for a variety of adapters. Any delay, such as searching for the correct adapter, has the potential of becoming a catastrophic situation for the patient. This position is also supported by TUV Product Service. Refer to Attachment 2, the TUV position paper, ***"Exposed pins at intracardiac catheters and its adapter cables".*** TUV discusses the use of an adapter that ends in an unprotected .080" pin configuration. At this time, Bard does not believe that this solution satisfies the intent of the performance standard.

3) ***Bard believes that the location of the lead wires for the Temporary Pacing Electrode catheters makes the device an acceptable candidate for an exemption.*** The device is located in the patient and the leads are in close proximity to the patient; typically extending not more than twelve inches from the patient. The proximity of the lead wires to the patient and the length of lead wire extending from the patient make it highly unlikely, if not impossible, that the lead wire could be accidentally plugged into a wall outlet.

D. Environmental Impact

Pursuant to 21 CFR 10.30 (b) C.R. Bard, Inc. claims the categorical exclusion from the environmental assessment requirements of 21 CFR 25.34.

E. Certification

I certify that in my capacity of Manager of Regulatory Affairs for C.R. Bard, Inc., that to the best of my knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature: Deborah L. Herrington 9/14/99

Name of Petitioner: Deborah L. Herrington
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ATTACHMENT 1

Instructions for Use

for the

Bard Temporary Pacing Electrode Catheters

Bard Temporary Pacing Electrode Catheter Information for Use

Read this document in its entirety prior to use.

Single use. ⊗

Sterile, non-pyrogenic unless package opened or damaged.

Caution: Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.

Description

Bard temporary pacing catheters are constructed of a woven or extruded polyurethane shaft with platinum or stainless steel electrodes. Certain catheters may incorporate one or more lumens for fluid infusion, pressure monitoring, blood sampling, or balloon inflation. The balloons are manufactured using latex material. Some product may be packaged with accessories such as a needle cannula, an ECG adapter, or a balloon inflation syringe.

Indications for use

Bard temporary pacing catheters are designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device. When an internal lumen is present (other than the one used for balloon inflation), it may be used for fluid infusion, pressure monitoring, or blood sampling.

Contraindications

None.

Warnings

General Warnings

These warnings apply to all Bard Electrophysiology temporary pacing electrode catheters.

- Inappropriate electrical connections, e.g. into a wall socket, may pose a serious risk of death or adverse health consequences. Please ensure that the catheter is connected as recommended for pacing or measuring intracardiac electrograms.
- This device should be used only by or under the supervision of physicians trained in the techniques of transvenous intracardiac studies and temporary pacing.
- This device is for one time use only. Reuse or resterilization can impair the structural integrity and/or performance of the catheter. Adverse patient reactions can also result from reuse.
- The risks of using temporary pacing catheters include those risks related to heart catheterization, such as thromboembolism, perforation, tamponade, and infection. The induction of an unintended arrhythmia is a known complication.

Warning for open lumen temporary pacing electrode catheters

If using an open lumen catheter, remove any guidewire/stylette prior to electrical stimulation.

Warnings for balloon temporary pacing electrode catheters

- Do not inflate balloon beyond stated maximum inflation capacity of 1.5 ml.
- Balloon must be completely deflated before withdrawal of the electrode catheter.
- If the balloon catheter has been inflated in vivo for more than one minute, completely deflate the balloon and reinflate it to the recommended capacity of 1.5 ml. This is recommended because carbon dioxide diffuses through the latex balloon.

Precautions

- Excessive bending, torquing, or kinking of the electrode catheter may cause damage to the catheter including damage to internal wires.
- When using a balloon catheter, use care when removing the protective sleeve from the distal portion of the catheter. Forced removal of this protective sleeve may result in damage to the balloon and the catheters structural integrity.
- When wiping down this catheter, use only sterile saline.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws.

Instructions for use

Inspection Instructions

1. Inspect the sterile package carefully for damage during transit or storage. Do not use the catheter if the package is damaged.
2. Visually inspect the catheter, under sterile conditions, for kinks in the catheter shaft, integrity of the connector, condition of electrodes, and any other damage.
3. In case of catheters with a balloon, under sterile conditions, remove the protective sheath and inflate the balloon with 1.5 ml of air or carbon dioxide. Use the inflation syringe included in the package. Completely deflate the balloon after the test.

Insertion Instructions using a needle cannula

1. Open the package and place the contents on a sterile field.
2. Prep the skin at the site of insertion and inject a local anesthetic.
3. Remove the protective guard from the needle cannula.

4. Enter the vein with the needle cannula. Simultaneous aspiration into a syringe will help confirm vessel entry.
5. Remove the syringe and the needle.
6. If using an open-lumen catheter, flush the catheter with a heparinized solution. Remove any stylette prior to insertion.
7. Using the aid of fluoroscopy or an ECG monitor, advance the catheter through the cannula to the desired position. If using a balloon catheter, inflate the balloon when the catheter is in the right atrium. Please note that the balloon can be inflated or deflated only when the stopcock is parallel to the catheter shaft. ***Do not pull the catheter back through the cannula as it may cause damage to the catheter.***
8. If using a balloon catheter, deflate the balloon after the catheter has reached the desired location.
9. Test the pacing characteristics for optimal pacing.
10. Pull the cannula back and secure it to the proximal end of the catheter.
11. Secure the electrode catheter in place at the insertion site.

Insertion instructions using a percutaneous introducer sheath

Follow the instructions, warnings, and precautions of the introducer manufacturer. If using a balloon temporary pacing catheter, use half or one French size larger introducer, unless otherwise recommended by the introducer manufacturer.

Electrical connections for measuring intracardiac ECGs

Connect the negative jack (marked "distal") to the V-lead of the ECG, and the positive jack (unmarked) to the positive terminal of the external pulse generator.

Electrical connections for pacing

Connect the negative jack (marked distal) to the negative terminal of the external pulse generator, and the positive jack (unmarked) to the positive terminal of the pulse generator.

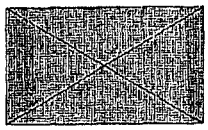
An issued or revision date and a revision number for these instructions are included for the user's information on the first page directly beneath the address and telephone number of Bard Electrophysiology. In the event two years have elapsed between the date and product use, the user should contact Bard Electrophysiology to see if additional information is available (Telephone number: 1-800-824-8724 [U.S.A.], 978-441-6202 [all others]).

*Trademark(s). For more trademark information, contact the manufacturer.

ATTACHMENT 2

TUV Product Service Position Paper

"Exposed pins at intracardiac catheters and its adapter cables"



other hand patients could also die if exposed pin connectors will be unintentional inserted in a mains socket outlet.

4. Risk analysis:

After an internal risk analysis has been performed it has to be mentioned that the emergency case „the need of connecting an external pacemaker" will much more occur as the hazard that „someone will insert the exposed pin connector in a mains outlet". Due to the fact that both risks could lead to patients death, the severity of the risks is equal.

5. Solution:

For devices which are already on the market according German MedGV or MDD 93/42/EEC it is the manufacturers decision if he will modify these device according the new requirements (using safety protected connectors and adequate outlets).
All devices, accessories, adapter-cables and catheters which will be shipped to the user after the transition period will end (31.12.2000) shall comply with the requirements for safety protected connectors. The manufacturers which have valid Annex III certificates shall apply for change notification of their products and certificates ASAP, at least at adequate time before the transition period ends (31.12.2000).
For new (upon today) type testing projects (not just small modifications on certified products) TÜV-PRODUCT SERVICE will not allow any longer exposed pin connectors, although there exist a legal transition period.
Due to the fact that there is a new unacceptable risk „connecting an external pacemaker in an emergency situation is not possible if safety protected connectors will be used", the manufacturers of catheters and its adapter-cables shall add adapters for each single safety protected connector of their product to ensure compatibility to existing external pacemakers which works only with exposed pin connectors.
Additional warnings shall be used in the catheters and adpater-cables manuals:
„If necessary insert and fix the adapters in the external pacemaker outlets to have a quick access to the patient heart for pacing in emergency cases. Alternatively keep a second external pacemaker available which accepts the use of safety protected connectors."
„Do never insert the catheter or adapter-cable connectors in mains outlets."
„During defibrillation >STAND CLEAR<."
„Exposed pin connectors of adapters shall not be plugged to any single connector, which is not in use."
„Anybody who perform electrophysiology intracardiac studies or external pacing or high-frequency ablation shall ensure the compatibility between intracardiac catheters/adapter-cables and the external pacemaker before the treatment will be started."
„Treatments where intracardiac catheters and its adapter-cables are used shall only be performed by special trained personal."

6. Remark:

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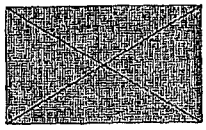

The above mentioned rationale is only valid for intracardiac catheters and its adapter-cables where the need of connecting an external pacemaker exist.
It is known, that the isolation barrier B-d is not in compliance with the standard if exposed pin adapters are used.

M. Schneeberg M. Sippl Dr. Schübel

M. Appel H. Ritscher

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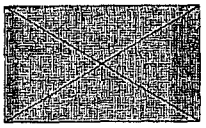

Exposed pins at intracardiac catheters and its adapter cables.

TÜV PRODUCT SERVICE position:

1. Applicable standards:
EN 60601-1:1990+A1:1993+A2:1995
IEC 60601-2-2:FDIS 1998 (Draft 3Ed.)
EN 60601-2-27:1994 (IEC 601-2-27:1994)
EN 60601-2-31:1995 (IEC 601-2-31:1994)
EN 60601-2-31/A1:1998 (IEC 601-2-31/A1:1997)

2. Definitions:

Exposed pin connector:	Single pole accessible connector of an intracardiac catheter or its adapter-cable which does not comply with EN 60601-1:1990+A1:1993+A2:1995 subclause 56.3.c. E.g. 2 mm exposed pin style.
Safety protected connector:	Single pole non accessible connector of an intracardiac catheter or its adapter-cable which complies with EN 60601-1:1990 +A1:1993 +A2:1995 subclause 56.3.c. E.g. DIN style connector according DIN 42802.

3. Problem:
The production of exposed pin connectors of intracardiac catheters and its adapter-cables for multiple purposes (ECG, HF-ablation, external pacing, intracardiac defibrillation) is forbidden according subclause 56.3.c of the general standard EN 60601-1:1990+A1:1993+A2:1995 and some part 2 standards.
The standard for external pacemakers EN 60601-2-31/A1:1998 (IEC 601-2-31/A1:1997) however starts to forbid exposed pin connectors first in 1998 with a transition period up to 01.01.2001 until this standard will be mandatory. This means that it is legal until 31.12.2000 to follow the valid standard EN 60601-2-31:1995 (IEC 601-2-31:1994) which allows exposed pin connectors, because this standard overrules the general standard EN 60601-1:1990+A1:1993+A2:1995.
The problem arises that intracardiac catheters and its adapter-cables for multiple purposes (ECG, HF-ablation, external pacing, intracardiac defibrillation) which will be designed according the new standard EN 60601-2-31/A1:1998 (IEC 601-2-31/A1:1997) with safety protected connectors are not compatible to currently available external pacemakers used in hospitals. Furthermore there is no hint in the EN 60601-2-31/A1:1998 (IEC 601-2-31/A1:1997) that adapters from safety protected connectors to exposed pin connectors are allowed to maintain compatibility to available external pacemakers.
This would lead to the risk that patients could die in an emergency situation. On the